

EC CERTIFICATE

for the Quality Assurance System



according the directive 93/42/EEC,
Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

Hansaton Akustik GmbH

Sachsenkamp 5, 20097 Hamburg, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50039-Z5-00, the decision dated 2016-01-25 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-01-31 to 2019-01-30

Certificate registration No.: 50039-16-05



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

DEKRA Certification GmbH Stuttgart; 2016-01-25

Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

Annex to the EC Certificate 50039-16-05 dated 2016-01-25

Revision status: 0

Date: 2016-01-31

Page 1 of 1



Devices/device categories included in the certificate

Class II a:

- BTE hearing instruments
- ITE hearing instruments
- Tinnitus instruments

